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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,122	04/07/2006	Ranga Madhavan Gurram	30251/09014 (fka DRF33028	9217
27530 7590 06/16/2010 Nelson Mullins Riley & Scarborough LLP IP Department 100 North Tryon Street 42nd Floor Charlotte, NC 28202-4000			EXAMINER ZUCKER, PAUL A	
			ART UNIT 1621	PAPER NUMBER
			MAIL DATE 06/16/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/575,122	Applicant(s) GURRAM ET AL.	
	Examiner Paul A. Zucker	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) 37-39 and 54- 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1- 10, 40, 53, 58 and 59 is/are rejected.
- 7) ☒ Claim(s) 12-36 and 41-52 is/are objected to.
- 8) ☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/29/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 14-36 and 41 (specifically) and 1-13, 39-55 and 58-59 (generically) in the reply filed on 18 November 2009 is acknowledged. The traversal is on the ground(s) that all of the compounds have a common structure. This is not found persuasive because the common structure that the compounds all share, as claimed in general formula (I), is not novel as shown by the rejections below and cannot, therefore, provide the special technical feature required for unity of invention. Applicants further argue (Remarks, response filed 27 May 2010) that the Examiner has not demonstrated a search burden. The Examiner responds that demonstration of a search burden is not a requirement for restriction in an International application. Applicants' arguments are therefore deemed unpersuasive. The requirement is still deemed proper and is therefore made FINAL. Claims 1-36, 40-53, 57 and 58 drawn to compounds and compositions thereof are examined below. Claims 36-39 and 54- 57 are held with drawn from consideration as being drawn to a non-elected invention.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 58 and 59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of dyslipidemia and diabetes, does not reasonably provide enablement for the prevention of these conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

These factors include, but are not limited to:

- a. The nature of the invention: The instantly claimed invention involves the prevention and /or treatment of the complex disease states diabetes and dyslipidemia. Since these disease states occur in complex biological contexts and can result from a variety of causative factors, it is difficult to determine which population of individuals should be treated in a preventative fashion before the appearance of any symptoms of the disease states. Since therapeutic treatments invariably are accompanied by associated risks, arbitrary treatment of a normal individual is undesirable. In addition, some

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forms of disease such some sources of disease, such as type I diabetes due to pancreatic disease are not preventable.

- b. The state of the prior art: The state of the prior does not allow one of ordinary skill in the art (the physician) to identify which, apparently normal, individuals are sufficiently at risk to warrant therapeutic administration of drugs which carry risks of their own as well as incur expense.
- c. The amount of direction provided by the inventor: The inventor provides direction only for the treatment of individuals (hamsters, rats and mice) which display disease symptoms. No direction for the identification of asymptomatic individuals at risk for the development of disease symptoms is provided.
- d. The existence of working examples: The only working examples provided are directed to the treatment of individuals (hamsters, rats and mice) which display disease symptoms. No working examples are provided that demonstrate a preventative effect in norm individuals.

Based upon the analysis above, the Examiner concludes that undue experimentation is required to make and use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 4. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention. Claim 2 recites the limitation "the stereoisomer" in line 1.

There is insufficient antecedent basis for this limitation in the claim.

5. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 has three periods, two of which follow the limitation "benzoxazolyl" on line 4. It is unclear which of the three sentences so defined Applicants intend to claim. Claim 3 is therefore rendered indefinite.
6. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites the limitation " 'Ar' may be" on line 4. It is unclear what other, un-recited, identities 'Ar' may adopt. Claim 3 is therefore rendered indefinite.

Claim Rejections - 35 USC § 102

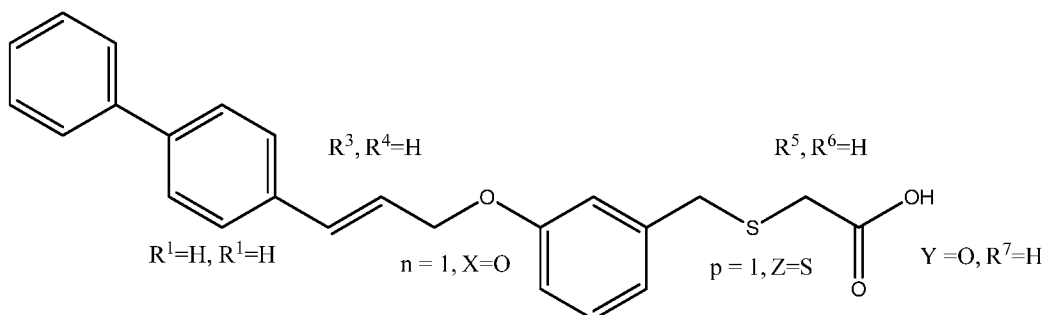
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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7. Claims 1- 9, 40, 53, 58 and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by Tajima et al (US 2003/0153579 08-2003). Tajima discloses (Paragraph [0804] (and [0388] for the corresponding ester)) a compound of the invention as shown here:



- with the appropriate instant variable group assignments shown. Tajima discloses (Abstract) the use of his compounds as agents for the treatment of diabetes and dyslipidemia. . Tajima discloses (Paragraphs [0292]-[[0302]) pharmaceutical compositions for use in medicines as well. Tajima therefore anticipates 1- 9, 40, 53, 58 and 59.
8. Claims 1- 10, 40, 53, 58 and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by Jeppesen et al (US 7,129,268-B2 10-2006). Jeppesen discloses (column 44, line 15- column 64, line 40, for example) compounds which correspond to those instantly claimed in which R¹, R²=halo, or halo alkyl, R³= p, n=1, R⁵, R⁶= H, X,Y, Z=O (see columns 47 and 8). Jeppesen discloses (column 36, line 52- column 38, line 24) pharmaceutical compositions. Jeppesen discloses (Abstract) PPAR activity for the compounds. Jeppeson therefore anticipates claims 1- 10, 40, 53, 58 and 59.

Claim Objections

9. Claim 2 is objected to because of the following informalities: The word “an” should be added before the word “enantiomer” in line 1. Appropriate correction is required.
10. Claims 12-36 and 41-52 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

11. The elected specie is free of art. Claims 12-36 and 41-52 are drawn to allowable subject matter. The following is a statement of reasons for the indication of allowable subject matter: The closest prior art, Tajima et al (US 2003/0153579 08-2003) and Jeppesen et al (US 7,129,268-B2 10-2006), either alone or in combination, neither discloses nor fairly suggests the instantly claimed compounds and compositions

Examiner's Comment

12. Upon rejoinder, method claims will be considered for compliance with 35 U.S.C. 112, 102 and 103. Applicants' should carefully amend the non-elected method claims, in light of the rejections applied, in their response to this action in order to assure expeditious passage to issue

Conclusion

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13. Claims 1-59 are pending. Claims 1- 10, 40, 53, 58 and 59 are rejected. Claims 12-36 and 41-52 are objected to. Claims 37-39 and 54- 57 are held withdrawn from consideration as being drawn to a nonelected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul A. Zucker/

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